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10/675,820	09/30/2003	Gary K. Michelson	101.0093-01000	6670
22882 7590 94/30/2009 MARTIN & FERRARO, LLP 1557 LAKE OPINES STREET, NE			EXAMINER	
			SWIGER III, JAMES L	
HARTVILLE, OH 44632			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/675,820 Filing Date: September 30, 2003 Appellant(s): MICHELSON, GARY K.

> Thomas H. Martin For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed 1/23/2009 appealing from the Office action mailed 7/25/2008

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on 1/23/2009 has been entered. It is noted that these claim amendments were entered to place the claims in better condition for appeal. This entry can be found on Advisory Action paper number 20090416-B.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

US Publication 2003/0135220 to Cauthen (07/2003)

5,846,249 Thompson 12-1998

US Publication 2003/0023209 to Gruskin et al. (01-2003)

US Publication 2003/0229401 to Mansouri et al. (12-2003)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 102(e) as being unpatentable over
Cauthen (US Pub 2003/0135220) in view of Thompson (US Patent 5,846,249). Cauthen
teaches a guard for use in spinal surgery having a body (12), having a leading end (17)
and opposite trailing end (15), the body having a first portion (18) and a second portion
(37) in a pivotal relationship with one another (see figs. 13 and 14), the proximate
leading end (17) having an open and closed position. The first (18) and second (37)
portions have at least in part opposed interior arcuate portion (14), respectively, and

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wherein the first and second portions define an opening for providing access to the disc space, a space that may be considered a tube and is adapted to provide access and guide therethrough a surgical instrument. The opening defined by the first and second portions of the body is generally circular but may also be elliptical (see paragraph 0039). Also the body's exterior surface has opposed upper and lower surfaces that are in part arcuate as well; wherein the exterior surface of the body has opposed side surfaces that are also in part arcuate and generally parallel; these sides also generally provide and are capable of providing a circular or elliptical cross section when in both the open and closed positions. The device may also be considered angled in the open position, at any given point between fully closed and fully open. The first and second portions also cooperatively engage each other when in a closed position (refer to Fig. 12). Further Cauthen teaches first and second portions that move rotatably to one another via a hinge, as they are associated with one another (par. 0034). Cauthen further describes that the device is able to create a disc space, as an 'open position' because of the ability of the device to rotatably articulate, creating a height (par. 0012) and allowing other devices to pass through. This orientation is considered along the mid-longitudinal axis. The device may also be secured/locked (par. 0045, line 15), and also comprises a collar (26, par 0040). Cauthen also teaches a body opening that has a height between 6-24 mm (par. 0038). Note that as claimed the opening as required for an instrument is between 8-25mm. However the range for Cauthen's device is 6-24. Therefore the device of Cauthen, as it is smaller, would be able to work within the situation as claimed by the applicant, meeting the size constraints. Cauthen teaches an opening between 6Application/Control Number: 10/675,820

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24mm and would by default be able to fit a device within the 8-20mm opening from the claimed invention. Further Cauthen teaches that the hollow tube may accommodate a bone removal device such as a reamer (disclosed in line 3 of paragraph 0038; or for an implant driver, also considered an insertion instrument (disclosed in lines 4-5 of paragraph 00390; or further a spinal implant (line 5 of paragraph 0039). With regards to the implant being partially bioresorbable, Cauthen further teaches that the spinal implant may be coated with a biocompatible material such as hydroxyapatite, which is inherently biocompatible/resorbable, as it has a similar chemical composition as human bone. The implant itself may also be made of a metal such as titanium (Par. 0042).

Cauthen et al. disclose the claimed invention except for more specifically an axis that passes through at least a portion of the pathway, allowing the two portions to articulate and distract vertebrae. Thompson discloses this feature, having two curved halves articulate about an axis that passes through at least a portion of the passageway (see joints via 123). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Cauthen having at least the axis that passes through at least a portion of the pathway in view of Thompson to better use the device to distract the vertebrae.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 and Thompson as applied to claim 21 above and further in view of Gruskin et al. (US 2003/0023209). Cauthen and Thompson disclose the claimed invention except for an implant that is incorporated with a material to prevent scarring. Gruskin et al. discloses a substance, namely a cross-linked polysaccharide having a positive charge

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that allows for the wound site to heal with less scarring. (See par. 0010). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen and Thompson an anti-scarring additive in view of Gruskin et al. to better allow the wound area to heal with less damage.

Claim 30 rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 and Thompson as applied to claim 21 above and further in view of Mansourt et al. (US 2003/0229401). Cauthen and Thompson disclose the claimed device of the spinal implant except for an implant having an antimicrobial agent. Mansouri et al. discloses an anti-microbial agent to prevent the colonization of bacteria on the surfaces of the implant or other parts of the device, or more specifically while treating a non-metallic medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the device of Cauthen and Thompson an anti-microbial agent to prevent infection and facilitate a more successful surgical application. (par. 0010).

(10) Response to Argument

Applicant's arguments filed 1/23/2009 with regards to claims 1-30 have been fully considered and are not persuasive. The claimed device still reads on prior art of record. In terms of applying art that are within the field of endeavor of one skilled in the art, both the devices of Cauthen and Thompson are considered assistive surgical devices for performing a given task. Cauthen teaches a device that distracts and provides access to a spinal area. Thompson is also a surgical device that distracts and provides access to a surgical site. Relocating the pin in the joint to a point and axis that passes through at

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least a portion of the pathway can provide a specific mechanical advantage of distracting the vertebrae in the similar way, as can Thompson in providing an axis in a certain location. Further, Thompson's interior arcuate portions distract in an orientation that realigns with an axis of the spine to distract vertebrae.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/JAMES L. SWIGER/

Examiner, Art Unit 3775

Conferees:

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775